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January 29, 2001

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

**RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The following information submitted in this amendment was requested by Dr. Steve Johnson, FDA Biopharmaceutical Reviewer, as a result of a teleconference held between FDA and Jones on 1/23/2001.

Average dissolution results at 45 minutes from one lot of each strength were submitted in Section 6.3 of the original NDA. Dr. Johnson requested that Jones provide the 45-minute dissolution data from the individual vessels for the following Levoxyl lots in support of the final averages previously reported. These data are provided as Attachment 1.

Lot Number	Strength	Lot Number	Strength	Lot Number	Strength
TT57	25 mcg	TT25	100 mcg	TT45	150 mcg
TT24	50 mcg	TT36	112 mcg	TT48	175 mcg
TT31	75 mcg	TT39	125 mcg	TT51	200 mcg
TT33	88 mcg	TT43	137 mcg	TT26	300 mcg

Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)

This application consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. Additionally desk copies are being sent to Mr. Steve McCort (Project Manager, FDA) and Dr. Steve Johnson (FDA Biopharmaceutic Reviewer).

By this letter, it is certified that a true copy of the application (including a copy of FDA application form 356h and a certification that the contents are a true copy of the application filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)



Nancy Cafmeyer
Director, Regulatory Affairs

Enclosure